bioretec

K062980

G 510(k) SUMMARY

For the Bioretec ActivaScrew™

NOV 2 2 2006

MANUFACTURER

Bioretec Ltd.
Hermiankatu 22, Modulight Building
FI-33720 Tampere
FINLAND

Contact person:
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Quality Manager
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Date prepared: September 27th, 2006

DEVICE NAME

Trade Name: Bioretec ActivaScrew™

Common Name: Bone, Fixation, Screw

ESTABLISHMENT REGISTRATION NUMBER

Bioretec Ltd. will register following FDA clearance.

DEVICE CLASSIFICATION AND PRODUCT CODE

Device Classification Name: Screw, Fixation, Bone

Classification Panel: Orthopedic

Regulation Number: 21 CFR 888.3040

Product Code: HWC

PREDICATE DEVICES

1. Inion OTPS™ Biodegradable Fixation System (K030900)
2. Bioretec ActivaPin™ (K061164)

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The **ActivaScrew™** is indicated for fixation of bone fractures, osteotomies, arthrodeses, bone grafts and osteochondral fractures of upper extremity, ankle and foot in the presence of

appropriate immobilization. Screws are available as fully and partially threaded in several different sizes, including diameters of 2.0 – 4.5 mm and lengths of 10 – 90 mm.

The **ActivaScrew™** is made of the completely bioabsorbable poly(L-lactide-co-glycolide) (PLGA) material, and they degrade *in vivo* by hydrolysis into alpha-hydroxy acids that are metabolized by the body. As the operated bone fracture or osteotomy gains strength during healing, the **ActivaScrew™** gradually loses its strength, however, maintaining its function at least 8 weeks. Bioabsorption takes place approximately within two years thus eliminating the need for implant removal surgery.

EQUIVALENCE TO MARKETED PRODUCTS

The ActivaScrew™ bioabsorbable screw is substantially equivalent to biodegradable screws, intended for similar indications, which have received 510(k) clearance.

The Bioretec ActivaScrew™ has the same intended use and principles of operation, and very similar design characteristic as the predicate device INION OTPS™ Biodegradable Fixation System screw implants (K030900). The material of the ActivaScrew™ is same as the material of the previously cleared ActivaPin™ (K061164). Any differences between ActivaScrew™ and these predicate devices do not raise any questions of safety and effectiveness.

Non-clinical tests and *in vitro* -testing determined that the ActivaScrew™ has substantially similar performance as compared to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bioretec Ltd.
% Ms. Mari Ruotsalainen
Quality Manger
Hermiankatu 22, Modulight Building
FI-33720 Tampere
Finland

NOV 2 2 2006

Re: K062980
Trade/Device Name: ActivaScrew™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 27, 2006
Received: September 29, 2006

Dear Ms. Ruotsalainen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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F Indications for Use Statement

Submitter: Bioretec Ltd.

510(k) Number:

Device Name: ActivaScrew™

Indications for Use:

The **ActivaScrew™** is indicated for fixation of bone fractures, osteotomies, arthrodeses, bone grafts and osteochondral fractures of upper extremity, ankle and foot in the presence of appropriate immobilization.

Contraindications:

1. Fractures and osteotomies of diaphyseal bone (except those in the hand and foot).

2. Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient's co-operation cannot be guaranteed.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062980